

### REMARKS

The only issue outstanding in the Office Action mailed November 25, 2003, is the rejection under 35 U.S.C §112. Reconsideration of this issue, in view of the following discussion, is respectfully requested. At the outset, the Examiner is thanked for withdrawing the restriction requirement, and examining all claims. Moreover, the Examiner is sincerely thanked for the time devoted to consider Applicants' proposed amendment, and for discussions with Applicants' representative concerning language which would overcome the remaining rejections. In view of these discussions, it is submitted that the present claim language obviates all of the rejections, as discussed more fully below.

Claims 1, 2, 5, 8-18, 23-26, 32 and 36-42 have been rejected under 35 U.S.C §112, second paragraph, reconsideration of this rejection is respectfully requested.

At page 2 of the Office Action, it is requested that the term "A process" be changed to "The process" for proper antecedent basis. Applicants have reviewed the claims, and do not see where any dependent claims do not already contain this language. If Applicants have overlooked a claim, they would be happy to amend same.

Also at page 2 of the Office Action, it is argued that claims 1 and 2 lack a "determination" step, as well as a positive recitation of a contact step between reagents and sample, and a correlation step which relates remanence magnetization to the presence of analyte. The Office Action moreover argues that it is unclear as to what is being detected to determine the presence of analyte, concluding that a determination of remanence magnetization "has no association with the presence of analytes."

**1. Determination Step:** It is respectfully submitted that a determination step is clearly present in claims 1 and 2, inasmuch as the claims recite "determining remanence magnetization" in the homogenous immunoassay.

**2. Contact Between Reagents and Sample:** Claims 1 and 2 have been clarified in order to indicate that the homogenous immunoassay has been contacted with the ferromagnetic or ferrimagnetic substances. While it is appreciated that the Examiner might prefer that the claim be recited in terms of individual steps ("contacting", "binding", "determining") Applicants have chosen to recite a claim which is *one-step* so as to provide stronger protection against potential infringers. The one-step claim requires simply that, in a sample in which a homogenous immunoassay is present, and in which a magnetic substance has been provided and bound to an analyte, the presence

of remanence magnetization is determined. As discussed more fully below, the presence of remanence magnetization indicates whether the analyte is present. It is this determination step which is an important feature of the presently claimed process. If Applicants were to recite a three-step claim, which requires contacting, binding and then determination, it is conceivable that each of two potential infringers could argue that infringement is avoided if, for example, one party merely contacts the sample with the magnetic substance, and then sends it to a second party to determine remanence magnetization and then report back the results. While, as the Examiner can no doubt appreciate, such would in essence infringe the presently claimed invention, infringement would be much more difficult to assert on a technical basis in this situation, since neither party would have carried out the entirety of the method. However, in the present claim, anyone who determines remanence magnetization in a sample which has previously been prepared as recited infringes the claim. Thus, end users of the process claimed would be infringers. It is for this ease of enforcing the invention that Applicants prefer to recite the patentable step of the claim in the present manner. However, it is submitted that the present claim language addresses all of the Examiner's concerns, inasmuch as it clarifies that the determination of remanence magnetization is in a sample containing the homogenous immunoassay, the analyte and the magnetic substance bound to the analyte, and that the presence of remanence magnetization indicates that the analyte is present.

**3. Association of Remanence Magnetization with Presence of Analyte:** As noted above, and as is apparent from the claims, it is the presence of remanence magnetization which indicates the presence of the analyte. Thus, the presence of the analyte is easily determinable by the presently claimed method.

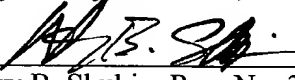
Finally, claim 40 has been clarified in order to provide proper antecedent basis.

In conclusion, it is submitted that all the claims herein clearly satisfy the requirements of 35 U.S.C §112. It is noted that the clarifications above have not changed the scope of the present claims, either literally or for purposes of the doctrine of equivalents. Withdrawal of all remaining rejections is respectfully requested.

Should the Examiner have any questions or comments, she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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